Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-F0BBE9B3-8662-431E-9930-B305A8538B6E_2_en-US
DOI: https://doi.org/10.31003/USPNF_M25500_02_01
DOI Ref: thu0y

Diethylpropion Hydrochloride Tablets

» Diethylpropion Hydrochloride Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{13}H_{19}NO \cdot HCl$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Diethylpropion Hydrochloride RS

Identification—

A: The Tablets meet the requirements under *Identification—Organic Nitrogenous Bases* ⟨181⟩.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation* as obtained in the *Assay*.

Dissolution ⟨711⟩—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{13}H_{19}NO \cdot HCl$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 253 nm of filtered portions of the solution under test, suitably diluted with 0.1 N hydrochloric acid, in comparison with a Standard solution having a known concentration of USP Diethylpropion Hydrochloride RS in the same medium.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{13}H_{19}NO \cdot HCl$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Phosphate buffer, Mobile phase, and *Chromatographic system*—Prepare as directed in the *Assay* under *Diethylpropion Hydrochloride*.

Standard preparation—Dissolve an accurately weighed quantity of USP Diethylpropion Hydrochloride RS in 0.1 N hydrochloric acid, and dilute quantitatively, and stepwise if necessary, with 0.1 N hydrochloric acid to obtain a stock solution having a known concentration of about 160 µg per mL. Transfer 5.0 mL of this stock solution to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix to obtain a solution having a known concentration of about 8 µg per mL.

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 40 mg of diethylpropion hydrochloride, to a 250-mL volumetric flask. Add 200 mL of 0.1 N hydrochloric acid, and stir with the aid of a stir bar for 45 minutes. Remove the stir bar, dilute with 0.1 N hydrochloric acid to volume, mix, and filter, discarding the first 25 mL of the filtrate. Transfer 5.0 mL of the filtrate to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. If necessary, filter the solution through a 0.7-µm porosity membrane filter.

System suitability preparation—Dissolve benzoic acid in 0.1 N hydrochloric acid to obtain a solution having a concentration of about 1 mg per mL. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, add 5.0 mL of the stock solution prepared as directed for the *Standard preparation*, dilute with *Mobile phase* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Diethylpropion Hydrochloride*. Calculate the quantity, in mg, of $C_{13}H_{19}NO \cdot HCl$ in the portion of Tablets taken by the formula:

$$5C(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Diethylpropion Hydrochloride RS in the *Standard preparation*, and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

We apologize for the inconvenience. The exact auxiliary information for this Documentary Standard is currently unavailable. Please contact Documentary Standards Support (stdsmonographs@usp.org) for assistance during this time.

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-F0BBE9B3-8662-431E-9930-B305A8538B6E_2_en-US
Previous DocID: GUID-F0BBE9B3-8662-431E-9930-B305A8538B6E_1_en-US
DOI: https://doi.org/10.31003/USPNF_M25500_02_01
DOI ref: thu0y